IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. 2:15-cv-00347 Judge Rodney Gilstrap
SANDOZ INC., Counterclaim Plaintiff, v. ALLERGAN SALES, LLC AND ALLERGAN, INC., Counterclaim Defendants.	

SANDOZ INC.'S MOTION FOR EARLIER TRIAL DATE
IN LIGHT OF AGREED CONSOLIDATION WITH C.A. 2:12-CV-00207-JRG

On July 30, 2015, this Court set a bench trial date of February 6, 2017. Sandoz respectfully seeks to move the trial date to May 2016, after consolidating this case with an earlier-filed related case. The earlier-filed case, which was stayed one month before its trial date in December 2013, involves the same parties, the same patent family, and the same accused product. Other cases set for trial at the July 30, 2015 status conferences received significantly earlier trial dates, in the fall of 2016. To the extent the Court set the trial at this later date in light of Patent Local Rule 3-8(g), this case should be treated differently because there is no applicable 30-month stay and because the majority of the patents in this case have been the subject of extensive litigation and discovery in earlier actions. As described in more detail below, to the

extent any additional fact discovery and claim construction is needed, a May 2016 bench trial allows more than ample time to add the patents in this case to the case that was ready for trial when stayed in 2013.

I. INTRODUCTION

This is the *third case* in a series of Hatch-Waxman lawsuits brought in this Court by Allergan, Inc. and/or Allergan Sales, LLC ("Allergan") against Sandoz to stop the launch of a competing generic medicine. Allergan wants to delay generic competition by delaying the present case. Like the two actions before it, this case stems from Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") for approval to market a generic version of Allergan's Combigan®, an ophthalmic combination of 0.2% brimonidine tartrate and 0.5% timolol maleate ("brim tim"). (*See* Compl. ¶ 27.) All the patents stem from a common parent application, share the same specification, and allegedly cover the same product.

The first of these lawsuits, *Brim Tim I*, involved four patents. It has been resolved through appeal, where the Federal Circuit invalidated Allergan's main patent, upheld the non-invalidity and infringement determination of one patent, and did not reach the other two patents-in-suit. After trial and while the appeals were pending, Sandoz designed around the one patent for which the infringement determination has been upheld.

The second of these lawsuits, *Brim Tim II*, involved two additional patents from the same parent application. That case was stayed in December 2013, only a month before trial. The Court stayed the case because the injunction in *Brim Tim I* prohibited Sandoz from launching its generic brim tim product, and the only relief Allergan sought in *Brim Tim II* was an identical injunction.

After *Brim Tim II* was stayed, Allergan obtained a seventh continuation patent. Allergan brought this case, *Brim Tim III*, to allege infringement of that seventh patent and for a declaration that Sandoz's design-around still infringes the patents in *Brim Tim I*. Accordingly, *Brim Tim III* involves the same parties and patents sharing the same specification as in *Brim Tim I* and *Brim Tim II*. The cases should be consolidated. Because the new issues in this case do not require extensive new discovery, an abbreviated case schedule creates significant efficiencies for the parties and the Court.

While Allergan recognizes these facts, and supports consolidating *Brim Tim II* and *Brim Tim III*, it wants to delay the trial date as long as possible because a later hearing provides Allergan with more time to market its product without the risk of generic competition. This is inappropriate. There is no 30-month stay in this latest case under the Hatch-Waxman framework. Allergan has already enjoyed such a stay. The majority of the patent claims have already been construed by this Court in *Brim Tim II*, and any remaining claim constructions will be straightforward. Discovery has been conducted on the majority of issues. Any remaining discovery can be completed quickly. Accordingly, Sandoz asks that this Court consolidate this action with 2:12-CV-00207-JRG and set a bench trial date around May 2016, which is more than ample time to prepare the few remaining issues in this matter.[1]

[1] The case could be ready for trial much sooner than May 2016. During multiple meet-and-confers with Allergan, Sandoz insisted the case could be ready for trial in 2015. Sandoz offered May 2016 as a compromise to accommodate Allergan's concerns that *Brim Tim III* requires additional discovery and claim construction. In this motion, Sandoz is asking the Court to agree with its compromise position. Allergan has never articulated why a trial date after May 2016 is necessary.

II. BACKGROUND AND PROCEDURAL HISTORY

A. The Brim Tim Patents

Allergan listed seven related patents in the FDA's "Orange Book" as formulations and methods of use for Combigan®, a drug commonly used to treat both glaucoma and ocular hypertension. Combigan® purportedly consists primarily of a combination of 0.2% brimonidine and 0.5% timolol: U.S. Patent Nos. 7,030,149 ("the '149 patent"), 7,320,976 ("the '976 patent"), the now-invalid 7,323,463 ("the '463 patent"), 7,642,258 ("the '258 patent"), 8,133,890 ("the '890 patent"), 8,354,409 ("the '409 patent"), and 8,748,425 ("the '425 patent"). (Countercl. ¶¶ 8, 15.)

Allergan agrees in principle that this *Brim Tim III* case, involving the '149, '258, '976, and newly-issued '425 patents should be consolidated with *Brim Tim II* (Case No. 2:12-CV-00207-JRG), where the '890 and '409 patents are already at issue. The accused product in *Brim Tim II* and *Brim Tim III* is the same. Consolidation would mean that this case would resolve issues of infringement and validity for all six of the remaining patents listed in the Orange Book. As explained below, however, the case would remain very straightforward as the parties have already litigated the vast majority of issues in the first two lawsuits.

B. The First Lawsuit: Brim Tim I

Sandoz submitted ANDA No. 91-087 on November 20, 2008, seeking FDA approval to market a generic version of Allergan's Combigan® product. Sandoz was the first to file an ANDA with a Paragraph IV certification for the then-listed Orange Book patents for Combigan®. (Countercl. ¶ 22.) In *Allergan, Inc. v. Sandoz Inc.*, Case No. 09-cv-0097-TJW (E.D. Tex. filed Apr. 7, 2009) ("*Brim Tim I*"), Allergan sued Sandoz in this District for allegedly infringing the '149, '976, '258, and '463 patents. Of the claims of the '149 patent, Allergan asserted claim 4 only.

On August 2, 2011, the first day of trial in *Brim Tim I*, Sandoz narrowed the issues for trial by stipulating to infringement under 35 U.S.C. § 271(e)(2). (Countercl. ¶ 23.) After a bench trial on the issue of invalidity, this Court held that the asserted patent claims were not invalid and issued an injunction preventing Sandoz from marketing its ANDA product. *See Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974, 1031-32 (E.D. Tex. 2011).

Sandoz appealed the non-invalidity judgments and the permanent injunction to the Federal Circuit. On May 1, 2013, a Federal Circuit panel unanimously held all six claims of the '463 patent to be invalid. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1295 (Fed. Cir. 2013). The '463 patent claimed the basic formulation for Combigan® – 0.2% brimonidine and 0.5% timolol, together in a single bottle. *Id.* at 1289.

The same divided panel upheld the validity of claim 4 of the '149 patent, the only claim of the '149 patent asserted at trial. *Id.* Claim 4 is an unusual claim. It is directed to "a method reducing" the number of daily doses of brimonidine "from 3 [times a day] to 2 times a day." The Federal Circuit upheld it. Then, relying on the validity of claim 4 of the '149 patent, the Federal Circuit deemed it "unnecessary" to address the '258 and '976 patents, failing to reach the merits of Sandoz's invalidity appeal. *Id.* at 1294 n.2 ("Because we conclude that claim 4 of the '149 patent is not invalid, [Sandoz] will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the '258 and '976 patents.").

Following the *Brim Tim I* trial, and subsequent appeal, on June 19, 2013, Sandoz amended its ANDA by submitting to the FDA a "section viii" "design-around" statement and amended product label. *See* 21 U.S.C. § 355(j)(2)(A)(viii); *see generally, Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (summarizing Hatch-Waxman laws and explaining the differences between "Paragraph IV" certifications and "section viii" statements).

Under Sandoz's amended ANDA, its formulation remained unchanged. Instead, the product label was changed so that it is no longer indicated for both glaucoma and ocular hypertension. The FDA later approved Sandoz's amended ANDA with the section viii statement. (Countercl. ¶ 26.) As amended, Sandoz's ANDA does not infringe claim 4 of the '149 patent, the only patent claim expressly found to be infringed and not invalid by the Federal Circuit in *Brim Tim I*. (*Id.*)

Based on this design-around, Sandoz filed a Rule 60(b)(5) motion in *Brim Tim I* to have the injunction modified so that it could launch its modified ANDA product, given that the section viii design-around rendered the '149 patent not infringed. (*Id.* ¶ 30.) Sandoz further requested that this Court hold the '258 and '976 patents invalid in light of the reasoning leading to the Federal Circuit's holding of invalidity of the '463 patent. This Court denied the first request on the ground that Sandoz's design-around was not an "unforeseen or unexpected" change in circumstances justifying relief under Rule 60(b)(5). *Allergan, Inc. v. Sandoz Inc.*, Nos. 2:09-CV-97, -348, -200, & -344, 2013 WL 6253669, at *3 (E.D. Tex. Dec. 3, 2013). This Court also ruled that it did not have jurisdiction to hear the merits of the invalidity arguments regarding the '258 and '976 patents because the Federal Circuit did not remand those issues to this Court. *Id.* at *2. Sandoz appealed this Court's denial of its Rule 60 motion to the Federal Circuit, which affirmed without an opinion. *Allergan, Inc. v. Sandoz Inc.*, 587 F. App'x 657 (Fed. Cir. 2014).

C. The Second Lawsuit: Brim Tim II

In *Allergan Sales, LLC v. Sandoz Inc.*, Case No. 2:12-CV-00207-JRG (E.D. Tex. filed Apr. 13, 2012) ("*Brim Tim II*"), Allergan brought suit against Sandoz with respect to the '809 and '409 patents. Due to the related nature of *Brim Tim I* and *Brim Tim II*, the parties agreed that fact discovery from *Brim Tim I* could be used in *Brim Tim II*. (Decl. of Brian Kramer ("Kramer Decl.") ¶ 2.) Indeed, the parties conducted only limited discovery into the specifics of the '809

and ’409 patents and Sandoz’s amended ANDA. (*Id.* ¶ 3.) Moreover, the bulk of fact discovery was conducted between June and August of 2013.

The Court held a Claim Construction hearing on June 28, 2013, and issued its Claim Construction Memorandum and Order on September 5, 2013. In its order, the Court largely sided with Sandoz regarding the construction of disputed terms in the ’890 and ’409 patents. Although the case was all but ready for trial by December 2013, the Court stayed the action pending the outcome of Sandoz’s appeal in *Brim Tim I*. *Allergan Sales, LLC v. Sandoz Inc.*, No. 2:12-cv-207-JRG (E.D. Tex. Jan. 22, 2015), ECF No. 213. That stay is no longer appropriate because the surviving patents involved in *Brim Tim I* are again at issue in this suit—namely, the ’149, ’258, and ’976 patents.

D. The Third Lawsuit: Brim Tim III

On January 23, 2015, Sandoz sent a Notice Letter to Allergan, noting that Sandoz continued to maintain its relevant Paragraph IV certifications in ANDA No. 91-087 and that it continued to seek approval to engage in the commercial manufacture, use, and sale of a generic version of Allergan’s Combigan® product before the expiration of the seven Orange Book-listed patents for Combigan®. (Countercl. ¶ 32.) Following the Notice Letter, Allergan brought this action for infringement of the three remaining *Brim Tim I* patents (the ’149, ’976, and ’258 patents), and the recently issued ’425 patent.

The ’425 patent in *Brim Tim III* is nearly identical to the ’890 and ’409 patents asserted in *Brim Tim II*. All three patents claim a reduction in side effects as a result of administering Combigan® as compared to the administration of brimonidine. For the ’425 patent, however, Allergan specifically drafted the patent claims to try to overcome invalidity issues identified by Sandoz in its *Brim Tim II* invalidity contentions and accepted by the Court in its September 5, 2013 Claim Construction Order. For example, whereas Claim 1 of the ’409 and ’890 patents

referred simply to "brimonidine," construed by this Court to mean "the chemical compound brimonidine, including its free base and tartrate salt forms," Claim 1 of the '425 patent specifically refers to "brimonidine tartrate." Similarly, whereas Claim 1 of the '409 and '890 patents referred simply to "timolol," construed by this Court to mean "the chemical compound timolol, including its free base, maleate salt, and tartrate salt forms," Claim 1 of the '425 patent specifically refers to "timolol free base."

III. A CONSOLIDATED CASE COULD BE EASILY READIED FOR TRIAL

As noted, the parties agree that this action should be consolidated with C.A. No. 2:12-CV-00207-JRG. Both actions involve the same parties, the same technology, and the same accused ANDA product. The single new patent asserted in this case (the '425 patent) is from the same family as the previously asserted patents; it is a continuation of the applications for the '409, '890, '976, '258, and '149 patents. As a result, the '425 patent's specification is identical to that of those previously litigated patents, and there is substantial overlap in the claims of the '890 and '409 patents.

The overlap in claims may be seen by reference to Claim 1 in both the '890 patent and the newly asserted '425 patent.

Claim From '890 Patent	Claim From '425 Patent
1. A **method of treating a patient** exhibiting elevated intraocular pressure (IOP), the method **comprising administering twice daily to an affected eye** a composition **comprising 0.2% w/v, brimonidine** and **0.5% w/v, timolol** in a single composition, **wherein said method results in a lower incidence of one or more adverse events**, as compared to brimonidine in the absence of timolol, where **the adverse event is selected from the group consisting of oral dryness, eye pruritus, foreign body sensation, allergic conjunctivitis, somnolence and**	1. A **method of treating a patient** with glaucoma or ocular hypertension **comprising administering twice daily to an affected eye** a single composition c**omprising 0.2% w/v brimonidine** tartrate and **0.5% w/v timolol** free base, **wherein said method reduces the incidence of one or more adverse events**, as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day wherein **the adverse event is selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritus,**

Claim From ’890 Patent	Claim From ’425 Patent
conjunctival folliculosis.	**allergic conjunctivitis, foreign body sensation, conjunctival folliculosis, and somnolence.**

These commonalities mean that much of the same prior art may be asserted against the new patent. Moreover, five of the six patents in the consolidated case have already been construed.[2] For the newly-asserted patent, claim construction issues overlap with those already addressed by this Court in *Brim Tim II*.

The strong relationship between the patents, and the large amount of ground already covered in the previous litigation, also means that discovery can be completed quickly. In *Brim Tim II*, the parties conducted fact discovery in a relatively short amount of time due, in part, to their agreement to use the discovery already conducted for *Brim Tim I*. To the extent additional discovery is needed, there will be considerable overlap. For example, many of the same witnesses, including the four common inventors and experts will be involved in both cases. Similarly, Sandoz’s current ANDA will be at issue in both cases.

IV. A CONSOLIDATED EARLIER TRIAL DATE IS IN THE INTERESTS OF JUSTICE

Faced with an injunction after it stipulated that its original ANDA infringed claim 4 of the ’149 patent, which was subsequently found not to be invalid, Sandoz designed around that claim and submitted an amendment to its ANDA. It has been trying for years now to get any court to assess the merits of whether its modified product infringes the Allergan patents. Sandoz believes that its modified product does not infringe Allergan’s patents, and seeks a quick

[2] Allergan has noted that it intends to raise a claim construction issue regarding the ’149 patent.

resolution in order to launch its product and provide the public with generic competition to Combigan®.

In a typical patent case, a defendant found to infringe is encouraged to design a modified product that does not infringe. It then has two options: (a) launch its modified product at the risk of being found in contempt if the modified product does not adequately avoid infringement, *see, e.g., TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 881-82 (Fed. Cir. 2011) (en banc), or (b) file a "motion to clarify or modify the injunction" prior to launching the modified product, thus avoiding the possible contempt finding, *id.* at 886. But because the FDA will not provide final approval of an ANDA while an injunction is in place, defendants in Hatch Waxman cases cannot launch their products at risk and pursue option (a).

Sandoz pursued option (b) after *Brim Tim I*, hoping that like all other defendants in patent cases, it could employ a relatively abbreviated path to determining whether its design-around infringes. This court essentially held that option (b) was not available in Hatch-Waxman cases, *see Brim Tim I*, 2013 WL 6253669, at *3, and the Federal Circuit affirmed. Sandoz accepts that decision. While a new lawsuit is apparently required to assess Sandoz's design-around, it does not follow that the new lawsuit cannot be expedited to reflect the discovery that has already taken place, the claims that have already been construed, and the remaining overlap from the prior litigations. The patent system encourages design-arounds. The Hatch-Waxman Act likewise encourages parties to design around patents through section viii "carve outs." An earlier trial date in this case would accommodate the benefits of design-arounds within the regulatory framework of the Hatch-Waxman Act.

V. CONCLUSION

A later trial date is a windfall for Allergan as Allergan seeks to delay generic competition and the marketing of Sandoz's generic version of brim tim. Given the speed with which this case

could be readied for trial, the interests of justice are better served by resolving the question of whether Sandoz's amended ANDA continues to infringe claim 4 of the '149 patent, and whether Allergan's remaining patents are invalid and/or not infringed at a May 2016 trial.

For the reasons outlined above, the action should proceed quickly in the interest of judicial efficiency, with a trial date at the Court's convenience as early as May 2016.[3]

Dated: August 13, 2015

By: /s/ *William E. Davis, III*

William E. Davis, III
Texas State Bar No. 24047416
THE DAVIS FIRM, PC
213 N. Fredonia Street, Suite 230
Longview, Texas 75601
Telephone: 903.230.9090
Facsimile: 903.230.9661
E-mail: BDavis@bdavisfirm.com

[3] Attached as Exhibit 1 to the Kramer Declaration is a proposed Docket Control Order based on such a schedule. If a May 2016 trial date is not acceptable to the Court, Sandoz will prepare with Allergan an alternative Docket Control Order based on whatever new trial date is acceptable to the Court. The parties will prepare a stipulation asking the Court to consolidate this case with C.A. No. 2:12-CV-00207-JRG.

Rachel Krevans
California Bar No. 116421
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: 415.268.7178
Facsimile: 415.268.7522
Email: RKrevans@mofo.com

Brian M. Kramer *(admitted pro hac vice)*
California Bar No. 212107
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
Telephone: 858.720 5100
Facsimile: 858.720.5188
Email: BMKramer@mofo.com

Attorneys for Defendant and Counterclaim Plaintiff SANDOZ INC.

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rules CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by e-mail, on this the 13th day of August, 2015.

/s/ William E. Davis, III
William E. Davis III

CERTIFICATE OF CONFERENCE

The undersigned certifies that counsel has complied with the meet and confer requirement in Local Rule CV-7(h), and that this motion is opposed.

/s/ William E. Davis, III
William E. Davis, III